
Controlled Clinical Trials

DESIGN, METHODS, AND ANALYSIS

Official Journal of the Society for Clinical Trials

Volume 8, 1987

Contents

PAUL L. CANNER, LAËL C. GATEWOOD, COLIN WHITE, JOHN M. LACHIN, and LESLIE J. SCHOENFIELD	
External Monitoring of a Data Coordinating Center: Experience of the National Cooperative Gallstone Study	1
R. BRIAN HAYNES and RENATO DANTES	
Patient Compliance and the Conduct and Interpretation of Therapeutic Trials	12
SAM WIEAND and TERRY THERNEAU	
A Two-Stage Design for Randomized Trials with Binary Outcomes	20
BARRY W. BROWN, JAY HERSON, E. NEELY ATKINSON, and M. ELIZABETH ROZELL	
Projection from Previous Studies: A Bayesian and Frequentist Compromise	29
CARINA HEISELBETZ and LUTZ EDLER	
A Sample Size Program for "Proving the Null Hypothesis"	45
G. ROSS LANGLEY, HEATHER J. SUTHERLAND, SAMUEL WONG, SALOMON MINKIN, HILARY A. LLEWELLYN-THOMAS, and JAMES E. TILL	
Why Are (or Are Not) Patients Given the Option to Enter Clinical Trials?	49
JOHN A. BLESSING, BRIAN N. BUNDY, PETER A. REESE, and ROGER L. PRIORE	
Experience with the Use of Generalized Data Base Management Systems in Cooperative Group Clinical Trials (A Project of the Gynecologic Oncology Group)	60
PER KRAGH ANDERSEN	
Conditional Power Calculations as an Aid in the Decision Whether to Continue a Clinical Trial	67
BARBARA S. HAWKINS	
Perusing the Literature	75
Book Review	85
Announcements	

BLOSSOM H. PATTERSON

- The Impact of Screening and Eliminating Preexisting Cases on Sample Size Requirements for Cancer Prevention Trials 87

E. van der PUTTEN, J. W. van der VELDEN, A. SIERS, and E. A. M. HAMERSMA, for the Cooperative Study Group of Dutch Datamanagers

- A Pilot Study on the Quality of Data Management in a Cancer Clinical Trial 96

CLAIR HAAKENSON, CAROL L. FYE, MIKE R. SATHER, and DENNIS J. TOUSSAINT

- The Investigator-Sponsored IND in Clinical Trials 101

BARRY R. DAVIS, J. DAVID CURB, BETTY TUNG, C. MORTON HAWKINS, SCOTT EHRMAN, JOHN FARMER, and MICHAEL MARTIN

- Standardized Physician Preparation of Death Certificates 110

LESLIE A. KALISH and COLIN B. BEGG

- The Impact of Treatment Allocation Procedures on Nominal Significance Levels and Bias 121

J. M. LONG, J. R. SLAGLE, A. S. LEON, M. W. WICK, J. P. MATTS, J. N.

KARNEGIS, J. K. BISSETT, H. S. SAWIN, and J. P. STEVENSON

- An Example of Expert Systems Applied to Clinical Trials: Analysis of Serial Graded Exercise ECG Test Data 136

L. DOUGLAS CASE, TIMOTHY M. MORGAN, and C. E. DAVIS

- Optimal Restricted Two-Stage Designs 146

Letter to the Editor

157

BARBARA S. HAWKINS

- Perusing the Literature 158

Announcement

175

JERRY HALPERN and BYRON WM. BROWN, JR.

- Designing Clinical Trials with Arbitrary Specification of Survival Functions and for the Log Rank or Generalized Wilcoxon Test 177

PETER PEDUZZI, H. TERESA HATCH, GARY JOHNSON, ANN CHARBONEAU, JOYCE PRITCHETT, and KATHERINE DETRE

- Coordinating Center Follow-up in the Veterans Administration Cooperative Study of Coronary Artery Bypass Surgery 190

STEVEN PIANTADOSI and BLOSSOM PATTERSON

- A Method for Predicting Accrual, Cost, and Paper Flow in Clinical Trials 202

DAVID WATERS, DONNA FREEDMAN, JACQUES LESPERANCE, PIERRE THEROUX, LISE LEMARBRE, BARBARA KAMM, MICHEL JOYAL, IHOR DYRDA, GILBERT GOSSELIN, GILLES HUDON, MARILYN HACHE, JUDITH HALLORAN, and RICHARD J. HAVEL

- Design Features of a Controlled Clinical Trial to Assess the Effect of a Calcium Entry Blocker Upon the Progression of Coronary Artery Disease 216

ALAN LEVITON, JENNY BAGLIVO, KARL C.K. KUBAN, ELIZABETH R. BROWN, and KALPATHY C. KRISHNAMOORTHY

- The Prophylactic Clinical Trial as an Epidemiologic Resource 243

BARBARA S. HAWKINS	
Perusing the Literature	255
Society for Clinical Trials: Officers, Board of Directors, Program Committee, and Secretariat	266
Final Program: Eighth Annual Meeting of the Society for Clinical Trials	267
Abstracts: Eighth Annual Meeting of the Society for Clinical Trials	280
Announcement: Ninth Annual Meeting for the Society for Clinical Trials	313
M. HALPERIN, K.K.G. LAN, E.C. WRIGHT, and M.A. FOULKES	
Stochastic Curtailing for Comparison of Slopes in Longitudinal Studies	315
ANNE I. GOLDMAN	
Issues in Designing Sequential Stopping Rules for Monitoring Side Effects in Clinical Trials	327
MICHAEL PHILLIPS and ALFREDO J. VAZQUEZ	
Abnormal Findings in "Normal" Research Volunteers	338
K. DICKERSIN, S. CHAN, T.C. CHALMERS, H.S. SACKS, and H. SMITH, JR.	
Publication Bias and Clinical Trials	343
DAVID H. BLANKENHORN, RUTH L. JOHNSON, SHARON A. NESSIM, STANLEY P. AZEN, MIGUEL E. SANMARCO, ROBERT H. SELZER, and the CLAS INVESTIGATORS and STAFF	
The Cholesterol Lowering Atherosclerosis Study (CLAS): Design, Methods, and Baseline Results	354
IAN CHALMERS and WILLIAM SILVERMAN	
Commentary: Professional and Public Double Standards on Clinical Experimentation	388
Letters to the Editor	392
BARBARA S. HAWKINS	
Perusing the Literature	395
Book Reviews	404
Announcement	411
Author Index to Volume 8	413
Subject Index to Volume 8	414
Volume Contents	